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August 7, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Ladies and Gentlemen:

RE: Docket No. 00N-1380

On behalf of the Orthopedic Surgical Manufacturers Association (OSMA), I am requesting that the comment period for the above-referenced docket be extended 90 days. This extension will provide interested parties adequate time to obtain and review the transcript from the August 2, 2000, public FDA meeting entitled "Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair" and to prepare comments to remarks made during the meeting, where appropriate. OSMA is very interested in this issue, as evidenced by our participation in the August 2 meeting; and it is our plan to submit written comments to the docket.

Thank you in advance for considering this request for an extension to the comment period for this docket. If you have any questions, please call me at 901-399-6142.

Regards,

Tom Craig
Tom Craig

cc: Ms. Kathy A. Eberhart
Center for Biologics Evaluation and Research (HFM-49)
Food and Drug Administration
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

00N-1380

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ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
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